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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,268	06/22/2001	Pananchukunath Manoj Kumar	RLL-178US	8724

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EXAMINER
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YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/888,268

Applicant(s)

KUMAR ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

**Acknowledgment of Papers Received:** Change of Address received 11/24/02, Request for reconsideration received 12/27/02.

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al (USPN 3,980,778) in view of Vilkov et al (USPN 5,807,579). Claims 1 – 9 are drawn to an oral formulation comprising loratadine with an average particle size between 0.1 and 15 microns. Claims 10 – 18 are drawn to a process for making the formulation of claims 1 – 9 where the drug is milled into the specific particle size.

Ayer et al discloses a drug formulation for oral and topical administration comprising fillers, binders and lubricants. One of the active ingredients can be an antihistamine, and the formulation calls for the active agent to be ball milled to sizes below 5 microns. The formulation comprises lactose, methylcellulose, starch, and magnesium stearate (col. 11, lin. 44 – 53; examples). The formulation differs from the claimed invention in that it does not name the antihistamine of applicant, though it is known in the art.

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What is lacking in the reference is a disclosure of a particular antihistamine, such as loratadine. Vilkov et al discloses a pharmaceutical tablet containing antihistamines such as azatadine and loratadine. The formulation further comprises other excipients, such as lubricants, fillers and plasticizers (col. 4, lin. 1 – 43).

One difference not addressed by the art is the surface area of the particles. It is known in the art that in order to increase the dissolution rate (and bioavailability) of a compound, the surface area must increase, thereby decreasing the particle size. In claims 1, 2, 10 and 12 applicant recites specific surface areas, along with particle sizes. It is the position of the examiner that in view of the knowledge in the art, which discloses the particle size of applicant that the recitation of surface area, one of ordinary skill in the art would be able to determine and obtain the surface area through routine experimentation. Barring a showing of criticality to the specific surface and unexpected results of said surface area, limitation is deemed non-critical and do not distinguish the claimed invention from the prior art.

Therefore one of ordinary skill in the art would have been motivated to incorporate the antihistamine of Vilkov into the formulation and process of Ayer in order to impart antihistamine properties onto the preparations. A skilled artisan would have followed the suggestion of Ayer to include antihistamines into the formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings of the art with the expected result of an oral tablet formulation with antihistamine, and improve dissolution properties.

*Response to Arguments*

3. Applicant's arguments filed 12/20/02 have been fully considered but they are not persuasive. Applicant argues that:

- a. The reference provide no teaching, suggestion, or motivation to produce a loratadine having the limitations of the inventions
- b. The combination of the references is merely hindsight reasoning.
- c. Vilkov does not solve the deficiencies of the Ayers

With regard to argument a., that the references do not produce a loratadine composition, the examiner disagrees. Ayer presents an oral composition that is ball milled (as in the presently claimed invention) to a particle size below 2 microns (within the limitations and scope of the claims). The reference was lacking in that it does not disclose loratadine, a well-known and useful antihistamine. Vilkov provides the loratadine in combination with other excipients. A skilled artisan would be able to combine the teachings seeing that Ayer suggests the use of antihistamines and Vilkov clearly provides antihistamine particles. It would be obvious to a skilled artisan to make a substitution of the active agent of Vilkov (loratadine) into the formulation of Ayer, in order to be process so as to improve the bioavailability.

Applicant makes a point that the references do not teach the surface are as claimed of the particle, yet it is well known that decreasing the particle size of a agent will increase the surface area. Decreasing the particle size by ball milling is well known in the art (as seen in Ayer), and making particular formulation substitutions is well within the level of ordinary skill in the art.

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In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to argument c., that Vilkov does not solve the deficiencies of the Ayer reference again the examiner disagrees. Ayer presents an oral composition with a particle size below 2 microns, and a suggestion of anti-histamine. Vilkov provides a specific antihistamine formulation in oral tablet form. Applicant is reminded that a reference need not contain each and every element of an invention in order to obviate it. The suggestion of an obvious and well-known component is sufficient for obviousness. Also Ayer is presented as an obviating reference. Had the reference comprised the antihistamine of the present invention, it would have been relied upon as anticipatory art under 35 USC 102.

#### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young  
April 15, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600